

REMARKS

Claims 1-21 are pending in the present application, claims 1-4, 6, 7, 18 and 19 are under examination, and claims 5, 8-17, 20 and 21 stand withdrawn.

**I. THE REJECTION OF CLAIMS 1-4, 6, 7, 18 AND 19
AS ANTICIPATED SHOULD BE WITHDRAWN**

Claims 1-4, 6, 7, 18 and 19 stand rejected as anticipated under 35 U.S.C. § 102(b) by Parkin *et al.*, AIDS 14:2877-2887 (2000) ("Parkin *et al.*"). In particular, the Examiner asserts that Parkin *et al.* discloses a method for assessing the likelihood of HIV-1 being hypersusceptible to treatment with amprenavir (APV/AMP). Applicants respectfully traverse.

Claims 1-4, 6, 7, 18 and 19 recite methods for determining whether a HIV-1 or an individual infected with HIV-1 has an increased likelihood of being hypersusceptible to treatment with a protease inhibitor, comprising detecting the presence or absence of a mutation in the HIV-1 protease at amino acid position 16, 20, 33, 36, 37, 39, 45, 65, 69, 77, 89 or 93, which is associated with hypersusceptibility to treatment with said protease inhibitor. As defined in the instant specification, "hypersusceptibility" refers to "an enhanced or *greater* susceptibility to a drug, an *increased* sensitivity to a drug or *decreased resistance* to a drug" (page 10, lines 9-10; emphasis added). The specification further defines what constitutes an "increased likelihood of being hypersusceptible":

"A virus has an 'increased likelihood of being hypersusceptible' to an anti-viral treatment if the virus has a property, for example a mutation, that is correlated with hypersusceptibility if a population of viruses having the property is, on average, more susceptible to the anti-viral treatment than an otherwise similar population of viruses lacking the property."

(Page 11, lines 15-20; emphasis added). Thus claims 1-4, 6, 7, 18 and 19 recite methods for determining an increased likelihood of enhanced or greater susceptibility to a protease inhibitor, or decreased resistance to a protease inhibitor, in a HIV-1 or an individual infected with HIV-1.

In contrast, Parkin *et al.* discloses methods of determining an increased likelihood of *reduced* susceptibility to a protease inhibitor in a HIV-1, or a subject infected with HIV-1.

Parkin *et al.* states:

“We sought to explore the potential relationship between reductions in drug susceptibility, detected before or at the time of viral load rebound, and virological outcome. In addition we characterized patterns of reduction in drug susceptibility after failure of a second line HAART regimen in treatment-experienced patients.”

(Parkin *et al.* at page 2878, left column, third paragraph; emphasis added). Nowhere in the cited reference does Parkin *et al.* disclose a method for assessing the likelihood of HIV-1 being hypersusceptible, or having an *increased* susceptibility to treatment with *any* protease inhibitor, much less an increased susceptibility to treatment with amprenavir. As such, Parkin *et al.* fails to teach each and every element of the invention defined by claims 1-4, 6, 7, 18 and 19, and thus cannot anticipate such claims. *See Merck & Co. v. Teva Pharmaceuticals USA, Inc.*, 68 USPQ2d 185 (Fed. Cir. 2003). Accordingly, Applicants respectfully request that the rejection of claims 1-4, 6, 7, 18 and 19 as anticipated by Parkin *et al.* be withdrawn.

II. CONCLUSION

In view of the foregoing, Applicants respectfully submit that the present application is in condition for allowance and earnestly request an early indication of the same. The Examiner is invited to call the undersigned attorney at (650) 739-3949 if a telephone call could help resolve any remaining items.

No fee is believed due with this response other than the fee for the extension of time for response. However, should the Commissioner determine otherwise, the Commissioner is hereby authorized to charge any required fee(s) to Jones Day Deposit Account No. 50-3013 (Order No. 949677-999014). A copy of this sheet is enclosed for such purpose.

Date: April 18, 2007

Respectfully submitted,


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